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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/28/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/760,379

Applicant(s)

RAUTH ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Status of the Claims***

1. Claims 1-11 and 13-15 are pending.

Applicants' amendment filed on April 1, 2002 (Paper No. 7) is acknowledged, and applicants' response and additional experimental data have been fully considered. Claims 1, 5-7, 10 and 13-15 have been amended, and claim 12 has been canceled.

**Rejection Withdrawn**

***Claim Rejections - 35 USC § 112***

2. The previous rejection of claims 1-15 under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' cancellation of claim 12, applicants' amendment to the claim, and applicants' response at pages 4-6 in Paper No. 7.

3. The previous rejection of claims 1-15 under 35 U.S.C.112, second paragraph, regarding lacking essential steps and various terms "and/or", "at least one surface", "and mixtures thereof", "wherein step (c) is performed by magnetic means", "magnetic means", "at least one washing step" and "at least one process step is automated", is withdrawn in view of applicants' cancellation of claim 12, applicants' amendment to the claim, and applicants' response at pages 6-8 in Paper No. 7.

***Claim Rejections - 35 USC § 102***

4. The previous rejection of claims 8 and 12 under 35 U.S.C. 102(b) as being anticipated by Belew *et al.* (J. Chromatography A, 679, 67-83 (1994)), is withdrawn in view of applicants' cancellation of claim 12, applicants' amendment to the claim, and applicants' response at pages 9-10 in Paper No. 7.

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5. The previous rejection of claims 7, 8 and 12 under 35 U.S.C. 102(e) as being anticipated by Smeds (U. S. Patent 6,005,082), is withdrawn in view of applicants' cancellation of claim 12, applicants' amendment to the claim, and applicants' response at pages 10-11 in Paper No. 7.

***Claim Rejections - 35 USC § 103***

6. The previous rejection of claims 1-14 under 35 U.S.C. 103(a) as being unpatentable over Wang *et al.* (U. S Patent 5,283,079) taken with Belew *et al.* (J. Chromatography A, 679, 67-83 (1994)) or Smeds (U. S. Patent 6,005,082), is withdrawn in view of applicants' cancellation of claim 12, applicants' amendment to the claim, and applicants' response at pages 12-13 in Paper No. 7.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6, for example, recites the limitation "the hydrophobic groups" in lines 1 and 2. There is insufficient antecedent basis for this limitation in claim 1. Claim 7 is included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which it depends. See also claim 8 for "hydrophilic groups", and claim 9 for "hydrophobic to hydrophilic groups".

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8. Claim 13 is indefinite because of the use of the term “the proteinaceous material and the solid phase are separated by magnetic beads”, it is not clear how magnetic beads separate the proteinaceous material and solid phase.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1-3, 6, 11 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Belew *et al.* (J. Chromatography A, 679, 67-83 (1994)).

Belew *et al.* teach a glycoprotein, recombinant human granulocyte-macrophage colony-stimulating factor (rhGM-CSF) from inclusion bodies produced by transformed E. coli cells is purified to homogeneity by a three-step chromatographic procedure using hydrophobic interaction chromatography (HIC) as the first step. In the HIC, Phenyl Sepharose 6 FF (high sub), which has average particle size of 90 µm (claims 2-3) and is agarose beads derivatized with phenyl group (claim 6), is used as packing material for column. The rhGM-CSF sample is dissolved in ammonium sulfate solution, applied to the HIC column, eluted the DNA contaminant with sodium phosphate-ammonium sulfate solution, and subsequently the bound protein is eluted with sodium phosphate (page 70, left column; page 74; Fig. 1; claims 1 and 11).

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The purified rhGM-CSF is analyzed by electrospray or laser desorption mass spectrometry (page 72; claim 14).

In response, applicants indicate the reference only shows the agarose material is derivatized with phenyl groups, and the coating dose not include hydroxyl group on the solid surface, thus the reference does not teach or suggest the existence of both hydrophobic and hydrophilic groups on the surface of a solid phase (pages 8-10 of the response). The argument is partially persuasive because the amended claim 1 does not recites the existence of both hydrophilic and hydrophobic groups on the solid surface, thus the rejection of claim 1 and certain dependent claims maintain, however, the rejection of claim 8, which recites the hydrophilic group on the solid surface, is withdrawn.

10. Claims 1-3, 6 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Smeds (U. S. Patent 6,005,082).

Smeds teaches recombinant coagulation factor VIII is purified by loading an aqueous solution containing factor VIII onto a hydrophobic interaction chromatography gel, which has aromatic or aliphatic group such as octyl or butyl on agarose matrices. For example, Butyl Sepharose 4 FF, which has average particle size of 90  $\mu\text{m}$  (claims 2-3) and is agarose beads derivatized with butyl group (claim 6), is used as packing material for column. The factor VIII solution is loaded onto the HIC column for adsorbing factor VIII to the gel surface, and the bound factor VIII is then eluted with buffer (column 4, line 49-column 5, line 37; column 6, lines 52-65; Examples; claims 1 and 11).

In response, applicants indicate the reference only shows the agarose material is derivatized with phenyl groups, and the coating dose not include hydroxyl group on the solid

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surface, thus the reference does not teach or suggest the existence of both hydrophobic and hydrophilic groups on the surface of a solid phase (pages 10-12 of the response). The argument is partially persuasive because the amended claim 1 does not recites the existence of both hydrophilic and hydrophobic groups on the solid surface, thus the rejection of claim 1 and certain dependent claims maintain, however, the rejection of claim 8, which recites the hydrophilic group on the solid surface, is withdrawn.

11. Claims 4, 5, 10 and 15 are rejected because they depend on a rejected claim.

***Conclusion***

12. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

*Karen Cochrane Carlson*  
KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER

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June 22, 2002